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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,239	12/08/2000	James Blake	02558P-001340US	1694
20350	7590	12/29/2005	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			LE, EMILY M	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/733,239

Applicant(s)

BLAKE ET AL.

Examiner

Emily Le

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 14-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>09/26/2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Claims 29-47 are cancelled. Claims 1-28 are pending. Claims 14-28 are withdrawn from consideration. Claims 1-13 are under examination.

Information Disclosure Statement

2. The information disclosure statements filed 08/29/01, re-filed 09/26/05, failed to comply with the provisions of 37 CFR 1.97 and/or 1.98 because an English translation of the St. Guttman reference is not provided. See MPEP § 609. In the absence of a translation, the Office cannot consider merits of the reference. Should consideration of said reference is desired by Applicant, Applicant is required to submit an English translation of the reference.

Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "highly acidic cleavage conditions" renders the claims indefinite. It is unclear what parameters and/or conditions encompassed by the cited recitation. In the instant, the metes and bounds of the cited recitation, particularly "highly", are undeterminable. Thus, in the absence of a clear understanding of the metes and bounds encompassed by the recitation, the claims are rendered indefinite.

The following indefinite finding is necessitated by Applicant's remarks. On page 10 of the Applicant's submission, Applicant argues the solid phase used in the art is different from those instantly claimed. The art teaches a solid phase, whereas the claims are directed at a solid phase that is "suitable for use in an immunological assay". In the instant, it is unclear how the intended use recited therein sets apart the solid phase recited in the claims and those in the art.

Additionally, on the same page, Applicant submits that the peptide referred to in claim 1 is in a form following (a) synthesis of the peptide, (b) cleavage of the peptide from a solid support used in such synthesis, and (c) immobilization of the peptide onto a solid phase. The interpretation provided by Applicant is not clearly set forth in the claims presented. Applicant is required to amend the claims to clearly reflect Applicant's discovery.

Claim Rejections - 35 USC § 102

5. The 102(b) rejection is withdrawn in view of Applicant's 09/26/05 submission, wherein Applicant amended the claims requiring the Cys residues be reversibly protected by a chemically reversible mean that is resistant to highly acidic cleavage

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conditions, and argues that the chemically reversible mean used by Cosand et al., benzyl, is not resistant to highly acidic cleavage conditions.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-4 and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cosand et al.,¹ in view of Brugger et al. (U.S. Patent No. 3798203.).

The claims are directed at a composition comprising an isolated peptide immobilized on a solid phase, said peptide having at least one epitope capable of binding antibodies. The peptide comprises an amino acid sequence of six to 50 amino acids; and two Cys residues, separated from each other by at least two but fewer than 20 non-Cys amino acid residues, wherein thiol groups of the Cys residues are reversibly protected from oxidation by a chemically reversible means resistant to highly acidic cleavage conditions. The claims later require the peptide to further comprise a third Cys residue at the N-terminus of the peptide, wherein the third Cys residue is not protected from oxidation. The claims also require the C-terminus of the peptide be amidated; limit the number of non-Cys residues between the protected Cys residues to 4 to 6 non-Cys residues; require the peptide be capable of binding antibodies to a retroviral transmembrane protein; which is later limited to SEQ ID NO: 1; and require the peptide

¹ Cosand et al. (U.S. Patent No. 4629783)

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to comprise at least seven contiguous amino acids of SEQ ID NO: 1. Additionally, the claims require the Cys residues be protected from oxidation by ethylcarbamoyl.

Cosand et al. teaches a composition comprising an isolated peptide immobilized on a solid phase. [Lines 54-64, column 9.] The peptide Cosand et al. teaches is of six to 50 amino acids, specifically 23 and 26 amino acid residues in length. [Peptides of the formula (I) and (V), respectively, wherein peptide of the formula (V) is the same as claimed SEQ ID NO: 1.] The peptide sequence comprises two Cys residues which are separated from each other by at least two but fewer than 20 non-Cys amino acid residues. Specifically, the peptide of the formula (I), the Cys residues are separated from each other by 20 non-Cys amino acid residues; and the peptide of the formula (V), the Cys residues are separated from each other by 5 non-Cys amino acid residues. The thiol groups of the Cys residues are reversibly protected from oxidation by a chemically reversibly mean. [Lines 54-64, column 9.] Both the peptides of Cosand et al. immunologically mimic proteins encoded by the LAV/HTLV-III retrovirus. Additionally, Cosand et al. also teaches the addition of a non-protected Cys residue to the N-terminus of the peptide of formula (I). The added non-protected Cys residue, if added to the peptide of formula (I) would be a third Cys residue. The C-terminus of the peptide of Cosand et al. is also amidated. [Lines 14-29 of column 4 and lines 30-39 of column 5.] Additionally, Cosand et al. teaches the immobilization of the peptide to a solid phase, t-butyloxy-carbonyl (BOCD)-methylbenzylcystein-phenyl-acetaminomethyl polystyrene/divinylbenzene resin.

In the instant, Cosand et al. teaches all that is encompassed by the cited claim, with one exception: it is not readily apparent if the chemically reversible means used by Cosand is resistant to highly acidic cleavage conditions, such as hydrofluoric acid. In the instant, Cosand et al. teaches the use of benzyl based compounds, however, it is unclear what type of benzyl based compounds Cosand et al. used. Such would be necessary to determine if the chemically reversible means used by Cosand et al. is resistant to highly acidic conditions. For example, if the benzyl based compound used by Cosand et al. is S-benzyl, then, Cosand does not teach a chemically reversible means that is resistant to highly acidic conditions. However, if the benzyl based compound used by Cosand et al. is N-benzyl derivatives, then, Cosand does teach a chemically reversible means that is resistant to highly acidic conditions. In the instant, such determination cannot be made, thus, a 103 rejection is necessary.

While it is not readily apparent if the chemically reversible means used by Cosand et al. is resistant to highly acidic conditions, the claimed invention remains obvious over the teachings of Cosand et al. in view of Brugger et al.

Brugger et al. demonstrates that chemically reversible means that is resistant to highly acidic conditions, such as ethylcarbamoyl, is well known in the art at the time the invention was made. In the instant, Brugger et al. teaches the use of ethylcarbamoyl in protecting Cys residues from oxidation. Thus, the use of ethylcarbamoyl to protect Cys residues from oxidation is well known in the art at the time the invention was made. Ergo, it would have been prima facie obvious for one of ordinary skill in the art to use ethylcarbamoyl as a chemically reversible means for protecting Cys residues from

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oxidation. One of ordinary skill in the art at the time the invention was made would have been motivated to do so to protect Cys residues from oxidation. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because ethylcarbamoyl is recognized in the art as a functional alternative to the benzyl based compounds used by Cosand et al. in protecting Cys residues from oxidation. Thus, in the absence of evidence to the contrary, one of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for producing the claimed invention.

In response to the rejection set forth in the previous office action, Applicant submits that neither Cosand et al. nor Brugger et al. teaches the immobilization of the peptide on a "solid phase suitable for use in an immunological assay", as required by the newly amended claims. Applicant asserts that the amendment distinguishes the recited solid phase from the solid phase used during synthesis of a peptide, such as those used by Cosand et al.

Applicant's submission has been considered, however, it is not found persuasive. As presented in the 112 Second rejection section of this office action, it is unclear how the intended use language present in the claims sets apart the solid phase recited in the claims and those in the art. In the instant, the claims require the peptide to be immobilized to a solid phase. Cosand et al. teaches the immobilization of the peptide to a solid phase, as acknowledged by Applicant in Applicant's 09/26/05 submission. In the last full paragraph, of page 10, of Applicant's 09/26/2005 submission, Applicant submits that Cosand et al. teaches the immobilization of the peptide to a "solid phase".

Additionally, the solid phase that is used by Cosand et al. is also suitable for use in an immunological assay.

Additionally, Applicant's also submits that the claimed invention provides several technical advantages over those taught in the art. The advantages are: the peptide is immobilized on a solid phase suitable for use in immunoassays and comprises Cys residues reversibly protected from oxidation by a chemically reversible means.

Applicant's submission has been considered, however, it is not found persuasive. In the instant, the advantages cited by Applicant are well recognized in the art; see the teachings of Cosand et al. Cosand et al. teaches the immobilization of the peptide on a solid phase and the Cys residues present in the peptide are reversibly protected from oxidation by a chemically reversible means. Thus, Applicant's submission is not found persuasive.

8. Claims 5 and 13 are rejected under 35 U.S.C. 103(a) as being Cosand et al. in view of Neurath et al. (U.S. Patent No. 4861588).

In response to the rejection set forth in the previous office action, Applicant submits that the rejection is to be obviated in view of the amendments are remarks set forth in Applicant's submission in response to the 35 U.S.C. 103(a) rejection over Cosand et al., in view of Brugger et al. (U.S. Patent No. 3798203.).

Applicant's submission has been considered, however, it is not sufficient to overcome the rejection for reason(s) set forth herein.

9. Claims 10-11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cosand et al.

In response to the rejection set forth in the previous office action, Applicant submits that the rejection is to be obviated in view of the amendments are remarks set forth in Applicant's submission in response to the 35 U.S.C. 103(a) rejection over Cosand et al., in view of Brugger et al. (U.S. Patent No. 3798203.).

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

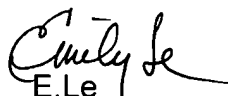
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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Art Unit 1648